



TGLN Quality System

TGLN

Quality Manual

Quality System Manual

Introduction

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Corporate Background

In 2000, the Premier's Advisory Board (PAB) was formed to increase and improve organ donation in Ontario. Following the recommendations of the PAB, Trillium Gift of Life Network (TGLN) was created in December 2000 by the Ontario government. TGLN assumed the role of Ontario's central organ and tissue donation agency and became operational in 2002. TGLN was challenged to significantly increase donation across Ontario and improve related processes and functions. TGLN's mandate is legislated by the Trillium Gift of Life Network Act.

As the Ontario agency responsible for organ and tissue donation and transplantation, TGLN's role and responsibilities includes but is not limited to:

- To plan, promote, coordinate and support organ and tissue donation
- Intake and management of organ and tissue donation referrals
- Clinical management, including donor suitability assessment
- Donor/Next-of-Kin approach and consent
- Establish and manage waiting lists for organ and tissue transplants, and a system of fair allocation
- Offer organs to Transplant Programs
- Offer tissues to Tissue Banks
- Provide governance to Transplant Programs
- Assess recipient conditions, both pre and post transplant
- Monitor the recipient wait lists for each organ group
- Raise awareness and educate
- Collect, analyze and publish data and information.

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Health Canada Regulations

Health Canada's Safety of Human Cells, Tissues and Organs for Transplantation Regulations took effect on December 7, 2007. Accordingly, TGLN registered with Health Canada as source establishment for deceased organs at that time. As a registered source establishment, TGLN is responsible for the safety of deceased organs in Ontario.

TGLN ensures that processing of deceased organs (including donor testing, suitability assessment, packaging, labeling and storage) is in compliance to the requirements of the Health Canada Regulations. As such, TGLN works with 'other entities' to ensure compliance to the Regulations; other entities include 7 serology laboratories and 3 organ recovery programs who conduct donor testing and packaging/labelling/storage respectively, on behalf of TGLN. The list of other entities is identified on TGLN's registration and renewal form with Health Canada.

Geography Served

TGLN works with health care professionals for identification, referral, clinical management and approach of substitute decision makers, plus recovery of potential and actual organ and tissue donors within Ontario hospitals. TGLN works with 69 designated hospital facilities including 55 corporations with level 3 intensive care units (ICU) and 14 corporations with level 2 ICU.

TGLN is responsible for allocating and offering donors (including out-of-province and out-of-country donors) to patients listed for transplantation with Ontario transplant programs. In the event that a donor cannot be used in Ontario, or as required by allocation algorithms, TGLN will offer organs to other organ procurement organizations outside of Ontario (Canada and USA).

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Key Accomplishments

Since TGLN first became operational in 2002, it has worked to increase the number of organ donors from 136 to 351 organ donors in 2016. As such, the number of transplants in Ontario has increased from 940 to 1302. This success is attributed to many key accomplishments, including:

- Expansion of mandatory reporting of all deaths in ventilated units in hospitals since April 2011 in addition to expanding from 21 hospital corporations to the current 55
- Special training for hospital coordinators who speak to donor families and introduction of a mandatory approach policy provincially
- Routinization of donation after cardio-circulatory death into provincial donation program
- Campaigns with multi-faith groups, workplace initiatives and improved public awareness of registration to encourage organ donation
- Development of Organ Specific Working Groups to improve donor acceptance
- Launch of re-approach strategy to affirm Health Care Professional declines

As the number of deceased organ donors is not yet able to meet the demand for the growing number of patients waiting for deceased organ transplantation, TGLN is committed to implementing and exploring innovative initiatives for the purposes of saving and enhancing more lives through the gift of organ and tissue donation.

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Quality Manual Certification

This Quality Manual defines the policies procedures and process instructions of the company's quality system. It is designed to be used as a basic reference document and outlines, in general terms, the controls in place to ensure that customer's requirements are met and that quality standards are maintained.

Implementation of the policies is by means of quality system procedures, quality process instructions and standard operating procedures which define the responsibilities and necessary controls that must be exercised for the various activities carried out during the course of TGLN's role.

The quality system documents defined in this manual are designed to meet the requirements of the ISO 9001:2008 (E) Quality Standard and the 2012 Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

Cross Reference Index to Quality Standards

The Quality Manual was numbered according to the general order of the ISO 9001:1994 Standard. Therefore, Sections 1 to 20 of the Quality Manual provide the content of Sections 4 to 8 of ISO 9001:2008.

Sections 21 and 22 of the manual were added to complement the existing twenty sections of the Quality Manual. These sections were added based on the criteria outlined in ISO 9004-2.

Quality System Registration Scope

TGLN is the provider of clinical services involved in the processing of deceased human organs for the Province of Ontario. The scope of this quality system focuses on these clinical services provided to the province.

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Company Location

TGLN operates primarily from one location as defined below. Organ and Tissue Donation Coordinators also reside at Tier 1 hospitals throughout the Province of Ontario. The quality system, as defined in this Quality Manual, applies to the location below:

Head office: 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9

Quality System Processes & Inter-Relationship

The Quality Management System (QMS) is shown in Exhibit 1. It is a series of inter-related processes, as shown by the QMS diagram. With the customer as the focus, there is a closed loop system linking Management Responsibility, Resource Management, Product Realization and Measurement, Analysis and Improvement.

Definitions

All Staff: Anyone employed at TGLN.

CAR/PAR: The corrective and preventative action process developed and implemented by TGLN as part of its QMS and which shall ensure that issues or deficiencies are identified, recorded and rectified.

Customer: The direct user or recipient (sometimes involuntary recipient) of a service. See “internal customer” and “external customer”. For the purposes of this policy, “client” will be considered synonymous with customer and encompasses people, business and organizations.

Customer Expectations: The assumptions that each customer has about the kind of service that will be provided during a transaction. The expectations are usually related to timeliness, reliability, accessibility, responsiveness and product/service quality.

External Customer: A person, business or organization that receives a service but is not part of the organization supplying it.

Internal Customer: A person, business or organization that receives a service and is part of the organization supplying it.

Non-Conformance: The non-fulfillment of specified requirements.

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Quality: The totality of features and characteristics of a product or services that bear on its ability to satisfy stated or implied needs.

Quality Policy: The overall quality intentions and direction of an organization regarding quality, as formally expressed by Senior Management.

Quality Process Instruction: A document that details a specified area of the quality system. It usually details a portion of a quality system procedure.

Quality System: The documented system that includes all processes required by the ISO 9001, the 2007 Health Canada Cells, Tissues and Organs Regulations.

Quality System Procedure: A document that specifies the purpose and scope of an activity: what shall be done and by whom; when, where and how it shall be done; what processes and documentation shall be used and how it shall be controlled.

Record: A document which is required to provide evidence of the quality of an item or activity and which has been identified for record retention in the quality system.

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Exhibit 1 - Quality Management System

